PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IEC040023PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN2004/000402	International filing date (*day/month/year*)	Priority date (*day/month/year*)

International Patent Classification (IPC) or national classification and IPC

IPC[7]: A61K31/185,31/19,31/194,A61K33/42,A61P37/00

Applicant

SHIAO,Shin-jen

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. *(sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:

   sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

   sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   Box No. I Basis of the report

   Box No. II Priority

   Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   Box No. IV Lack of unity of invention

   Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   Box No. VI Certain documents cited

   Box No. VII Certain defects in the international application

   Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.Nov.2004(23.11.2004)	23.Aug.2005(23.08.2005)

Name and mailing address of the IPEA/CN	Authorized officer
The State Intellectual Property Office, the P.R.China, 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088	LIU,Qiming

Facsimile No. 86-10-62019451 | Telephone No. 86-10-62085248

Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/000402

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

the international application in the language in which it was filed

a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

international search (Rules 12.3(a) and 23.1(b))

publication of the international application (Rule 12.4(a))

international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

the international application as originally filed/furnished

the description:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

the claims:

pages _____ as originally filed/furnished

pages * _____ as amended (together with any statement)under Article 19

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

the drawings:

pages _____ as originally filed/furnished

pages * _____ received by this Authority on _____

pages * _____ received by this Authority on _____

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

the description, pages _____

the claims, Nos. _____

the drawings, sheets/figs _____

the sequence listing *(specify)*: _____

any table(s) related to sequence listing *(specify)*: _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____

the claims, Nos. 1,13,17,22,24

the drawings, sheets/figs _____

the sequence listing *(specify)*: _____

any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

This questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious),or to be industrially applicable have not been examined in respect of:

the entire international application

claims Nos. 8-12,24-30,54

because:

the said claims Nos. 54

relate to the following subject matter which does not require an international preliminary examination*(specify)*:
The subject-mtter of claim 54 is directed to a method of therapeutical treatment (Article 17(2)(a)(i) and Rule 39(iv)PCT).

said claims Nos. 8-12,24

are so unclear that no meaningful opinion could be formed *(specify)*:
see Box No. VIII

said claims Nos. 25-30 are so inadequately supported

by the description that no meaningful opinion could be formed.
see Box No. III

no international search report has been established for said claims Nos.

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

See Supplemental Box for further details.

See Supplemental Box for further details.

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. IV Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

   restricted the claims

   paid additional fees

   paid additional fees under protest and, where applicable, the protest fee

   paid additional fees under protest but the applicable protest fee was not paid

   neither restricted nor paid additional fees

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

complied with.

not complied with for the following reasons:

The independent claim 1 relates to pharmaceutical composition comprising an edible acid and/ or acidic salt, the independent claim 21 relates to the use of edible acid and/ or the acidic salt in the manufature of pharmaceutical composition,the independent claim 25 relates to the use of edible acid and/ or the acidic salt in the manufature of food, beverage or health care material, the independent claim 31,33 relate to the method of the manufature of protein denaturation food and food reducing risk of allergy, respectively. the independent claim 51 relates to the method reducing allergen of object. Because independent claim 1, 21,51 and independent claim 25,31 and 33 contain no the same or corresponding special technical feature, claims above don't meet the request of unity. At the same time, because the independent claim 1 has no novelty, thus dependent claim 2 and 3 also contain no the same or corresponding special technical feature,claim 2 and 3 don't meet the request of unity .

4. Consequently, this report has been established in respect of the following parts of the international application:

all parts.

the parts relating to claims Nos. _____

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims	23, 37, 42, 51-53	YES
	Claims	1-7, 13-22, 31-36, 38-41, 43-50	NO
Inventive step (IS)	Claims	23, 51-53	YES
	Claims	1-7, 13-22, 31-50	NO

Industrial applicability (IA)	Claims	1-7, 13-23, 31-53	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document:

D1: US 6297244 B

D2: WO 0128556 A

D3: EP 1197152 A

D4: CN 1356393 A

D5: CN 1039709 A

D6: CHEN Xinqian et al, XINBIANYAOXUE, PEOPLE HYGIENE PUBLISHING COMPANY, 14th edition, page 476-477

D1 discloses a composition compring acidic substance which is selected from the group consisting of ascorbic acid, critric acid, tartaric acid, lactic acid, malic acid, and malic acid and phosphoric acid(see claim 4 of D1). It also discloses that the content of the acidic substance is in the range of about 0.2% by weight to 10% by weight of the pharmaceutical composition(see claim 7 of D1). D2 dicloses a low irritation nasal composition for prevention and treatment of cold and influenza viruses, which may comprise ascorbic, fumaric,lactic and other organic acid. It also discloses that the said composition is administered by spraying(see claim 2,7 of D2). Therefore, the subject-matter of claims 1-7,13-20,43-50 is not new in the sense of Article 33(2) PCT.

D3 discloses a dairy product, to which a reducing agent such as ascorbic acid is added (see claim 4,7 of D3). Therefore, D3 is novelty destroying for the subject of claims 31-35,38-40(Article 33(2)PCT) . Seleccting a suitable concentration of the edible acid and/or acidic salt seems to be obvious to the person skilled in the art. Therefore claim 42 can't be cinsidered as involving an inventive step(Article 33(3)PCT).

D4 discloses a method of preparing extract of small miscellaneous sea fish , wherein the preparation process includes adding phosphate buffering system.(see claim 1 of D4).therefore, the subject-matter of claim 36 isn't new in the sense of Article 33(2) PCT. Seleccting a suitable concentration of the edible acid and/or acidic salt seems to be obvious to the person skilled in the art. Therefore claim 37 can't be cinsidered as involving an inventive step(Article 33(3)PCT).

D5 discloses a method of making MAIFANSHI coke beverage to which is added phosphoric acid(see claim 1 of D5). Therefore, D5 is novelty destroying for the subject of claims 41(Article 33(2)PCT) .

D6 discloses that ascorbic acid is used in treatment against allergic dermatosis(see page 476-477 of D6). Therefore, D6 is novelty destroying for the subject of claims 21-22(Article 33(2)PCT) .

The above documents don't disclose or even suggest that edible acid and/or acidic salt can be used to reduce the sensitivity of the object which is in contact with the skin of the subject being treated, nor disclose or even suggest that inorganic acid and/or acidic salt can be used to treat or relieve immunological diseases . Therefore claims 23,51-53 involve both novelty and inventive step.

Claims 1-7,13-23,31-53 are industrially applicable. For the assessment of the present claim 54 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treament, but may allow claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 8-12,21-24 are unclear(Article 6 PCT).

The subject-matter of claims 8-10 is pharmaceutical composition, while the characterizing position thereof is food / beverage. It isn't clear that the subject-matter of claims 8-10 relates to pharmaceutical composition or food / beverage, thereby rendering the definition of the subject-matter of said claims unclear (Article 34(4)(a)(ii) PCT).

The subject-matter of claims 11-12 is pharmaceutical composition, while in the characterizing position thereof the edible acid and/or the acidic salt is in the form the acidic fruit. It isn't clear that subject-matter of claims 11-12 is pharmaceutical composition or fruit, thereby rendering the definition of the subject-matter of said claims unclear (Article 34(4)(a)(ii) PCT).

In the characterizing position of claim 24 the organic acid and/or acidic salt is acidic fruit, but it is apparent that organic acid and/or acidic salt are chemistry substances, and acidic fruit isn't chemistry substance. Therefore claim 24 isn't clear thereby rendering the definition of the subject-matter of said claims unclear (Article 34(4)(a)(ii) PCT).

The expression "immunological disease" in claim 21 is indefinite, thereby rendering the definition of the subject-matter of claim 21 and the depending claims 22-24 unclear (Article 6 PCT).

Claims 25-30 are inadequately supported by the description(Article 6 PCT) .

The subject-matter of claims 25-30 relates to the use in the manufacture of food, beverage or health-care product for use in improving human immunity. However, there is no any test data in the description that shows that the food, beverage or health-care product can improve human immunity. Therefore, claims 25-30 are not fully supported by the description (Article 34(4)(a)(ii) PCT).

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International application No.

Supplemental Box

In the amendment of the independent claims 1,13,17,22 and 24 , "edible acid" is changed to "edible carboylic acid", the technical feature "edible carboylic acid" was not specifically made mention of in the initial description and claims , and "carboylic acid" is not the same concept as "organic acid" in the initial application document, Therefore, the amendment is beyond the scope of the disclosure contained international application document when it is filed (A34(2)(b)PCT).